Calendar No. 1146

100TH CONGRESS *2d Session* | SENATE | REPORT 100-600

FDA REVITALIZATION ACT

OCTOBER 21 (legislative day, OCTOBER 18), 1988.—Ordered to be printed

Mr. KENNEDY, from the Committee on Labor and Human Resources, submitted the following

REPORT

[To accompany S. 2468]

The Committee on Labor and Human Resources, to which was referred the bill (S. 2468) to revitalize the Food and Drug Administration, and for other purposes, having considered the same, reports favorably thereon with an amendment in the nature of a substitute and recommends that the bill as amended do pass.

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I. SUMMARY OF THE BILL

The bill, S. 2468 amends sections of the Food, Drug and Cosmetic Act; the Medical Device Amendments; and the Public Health Service Act. Title I amends Chapter VII of the Food, Drug, and Cosmetic Act and establishes the Secretary of the Department of Health and Human Services as the authority for approving real property transactions proposed by the FDA. Title II amends Section 241 of the Public Health Service Act and provides a new section to establish a Senior Biomedical Scientific Service under which the Secretary appoints experts trained in biomedical sciences to perform administrative, clinical, and regulatory duties in exchange for en-

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hanced compensation and retirement plans. Title III authorizes the addition of 350 FTEs to the Food and Drug Administration. Title IV provides a new subsection to Section 10 of the Medical Device Amendment and authorizes a total of $18,000,000 to be appropriated for small business training and technical assistance. Title V amends Chapter VII of the Food, Drug, and Cosmetic Act and sets forth the conditions under which the Secretary may use public or private facilities intended to advance the FDA's goals. A total of $10,000,000 is authorized to be appropriated for FY89, with recommendations for reauthorization for FY90 and FY91. Title VI amends subtitle IX of the Food, Drug and Cosmetic Act and provides grants to public and private nonprofit academic institutions to train health professionals and scientists in the area of regulatory review medicine. The Secretary will be authorized to make grants to public and private non-profit academic institutions to train health professionals and scientists in the field of regulatory review medicine. Upon completion of training, participants are obligated to work for the Food and Drug Administration for a period equal to 2 months for each month they received training funds.

A Science Training Grant Loan Repayment Program will be created to help address resource needs of the Food and Drug Administration. The principle applicants for this program will be scientists and health professionals who have been trained in the field of regulatory review medicine. Title VII amends chapter IX of the Food, Drug, and Cosmetic Act by adding a new section which authorizes the Commissioner of Food and Drugs to appoint members of technical and scientific review groups. Under the provisions of the Federal Advisory Committee Act such review groups must receive direction from the Secretary of the Health and Human Services.

II. Background and Need for Legislation

Fifty years of scientific advancement and biotechnological discoveries have transpired since the Food, Drug and Cosmetic Act of 1938 was passed, bringing to the nation significant health improvements and economic profits. The premarket approval and postmarket surveillance activities of the Food and Drug Administration have since enabled the nation to increase its consumption of safe and healthy foods, drugs, cosmetics, biologics, and medical apparatus. The surge of food and nutrition activities of the 1940s, the phenomenal growth in pharmaceuticals during the 1950s and 1960s, the Medical Device Amendments of 1976, the biotechnological advances of the 1980s, and the continuing AIDS epidemic of the 1990s attest to the changing needs of an agency directed to protect the public's health.

As its mission to protect the public health continues, the FDA seeks to evolve and adapt to the science and technology spurts of the late 20th century at a pace that will bolster the Nation's international competitiveness in the 21st century. Facing the challenge to strike a balance between science and regulation is a necessary but costly task for policymakers to consider. The manner in which the FDA meets this challenge will be largely influenced by Federal policies and programs supporting biomedical research and regulatory training needs within the agency.

REAL PROPERTY

Real property disposition for Federal agencies, including the FDA, must be authorized by the Secretary of the Department of Health and Human Services, and disbursed by the General Services Administration (21 U.S.C. 371). The FDA proposed that the current law could be amended to allow the agency increased flexibility to shift its laboratory and facilities space, whenever necessary.

In June 1986, the FDA proposed to close certain facilities that it rented from the General Services Administration (GSA). The House Committee on Appropriations rejected the proposal and decided that the Secretary would remain in authority on such matters and, it recommended that no laboratory space re-assignments be made or facilities closed by the FDA until it has submitted a cost-savings analysis of the proposed plan. Also, the Committee directed the FDA to review the findings of a soon-to-be published report by the General Accounting Office (GAO), which will evaluate the efficiency of FDA's proposed building and facility restructuring.

In July 1986, the FDA recommended to the Senate Committee on Appropriations a proposal to consolidate its "Salaries and Expenses" account with its "Rental Payments" and "Building Facilities" accounts. The major benefit of this account consolidation would be greater flexibility for the FDA's use of funds for program expenses. All Federal facilities are accounted for by the General Services Administration under current laws (42 U.S.C 252 and 40 U.S.C. 751). After some discussion, the Senate Committee on Appropriations decided that for the sake of sound administrative and accounting procedures the FDA would maintain each of the three accounts separately, and under the jurisdiction of the Secretary, with the GSA.

In its Justification of Appropriations Estimates for 1988 the FDA stated that improvements and repairs to FDA headquarters and field facilities were necessary to enhance the agency's ability to carry out its regulatory activities. A total of $1,450,000 was requested to maintain ongoing activities and to initiate improvement projects from laboratory renovations to road and roof repairs.

SENIOR BIOMEDICAL SCIENTIFIC SERVICE

The FDA maintains that as the "gatekeeper of technology transfer from the laboratory to the marketplace," it requires distinguished scientific talent from fields of study related to biotechnological and medicine. In its Plan for Action II (1987), the agency cited the aging of the current work force as a factor that continues to diminish its ranks of highly qualified scientists. The average age of the FDA professional scientist is about 46 years. Mid-career and advanced level scientists are often attracted by the compensations offered to them by the private sector, which is competition the FDA cannot match. In the short-term, attrition and retirement are expected to shrink the pool of experts employed on a full-time basis. Meanwhile, fewer American students are pursuing careers in medicine and biotechnology, but the FDA proposes to train personnel and others to become experts. It aims to muster human resources and scientific talents within the agency and proposes to: (1) exam-

ine its personnel management practices; (2) recruit and retain its scientific staff; (3) identify development and training needs of its managers and implement appropriate programs; and (4) continue its Commissioner's Advancement Program (CAP) which seeks to help its employees advance through career enhancement.

FULL-TIME EQUIVALENTS

Still recovering from the 12 percent decrease in the total number of staff and budget dollars during the years 1979 through 1983, the FDA requests for additional staff are in keeping with its increased workload. In 1986, over fifty percent of the total FTEs were allocated to the Office of Regulatory Affairs (38 percent) and the Center for Drugs and Biologics (20 percent). In FY88 total FTEs are expected to rise to a level slightly higher than in 1986 to a total of 6,689. As of June 1988, the revised ceiling for FTEs was 7,076. In its Justification of Appropriations Estimates for 1988, the agency anticipates a need to increase the number of FTEs in order to respond to new drug review approval processes, expedite the medical device review process, to "provide rapid product application reviews for products related to AIDS," and to "strengthen food surveillance activities in an effort to prevent the recurrence of emergencies." Table 1 shows that the three divisions with the highest number of FTEs in 1986 were the Office of Regulatory Affairs, (2,705), the Center for Drugs and Biologics (1,379) and the Center for Food Safety and Applied Nutrition (815). Corresponding with this expenditure of human-work-hours is the public's demand for information. In 1986, the Office of Consumer Affairs processed the largest number of public inquiries on issues related to human foods and cosmetics (28,322 inquiries) and human drugs and biologics (24,402 inquiries).

TABLE 1.—DISTRIBUTION OF FDA PERSONNEL IN TERMS OF FULL-TIME EQUIVALENTS [FTE'S] AS OF SEPT. 27, 1986

	Expended to date	Ceiling for fiscal year	Variance [1]
Organization:			
Office of Commissioner	62.1	58.5	3.6
Office of Consumer Affairs	31.6	24.9	6.7
Office of Planning and Evaluation	46.4	42.4	4.0
Office of Legislative Affairs	30.2	33.3	−3.1
Office of Public Affairs	60.8	55.6	5.2
Office of Health Affairs	46.4	46.9	−.5
Office of Management of Operations	531.9	545.4	−13.5
Office of Regulatory Affairs	2,705.8	2,709.0	−3.2
National Center for Toxicologic Research	284.3	281.0	3.3
Center for Food Safety and Applied Nutrition	815.1	820.0	−4.9
Center for Drugs and Biologics	1,379.4	1,419.0	−39.6
Center for Veterinary Medicine	243.3	247.0	−3.7
Center for Devices and Radiological Health	762.2	766.0	−3.8
Total	6,999.5	7,049.0	−49.5

[1] Variance: Expended versus ceiling.

Source: Food and Drug Administration.

SMALL BUSINESS TRAINING AND TECHNICAL ASSISTANCE

Given the competitive environment, small businesses may have difficulty keeping up with the regulatory requirements of the Medical Device Amendments. The Medical Device Amendments of 1976 (P. L. 94-295) established an office to provide technical assistance and information to small business. Up until now the agency has provided small business manufacturers with assistance in filling applications, answering questions, and gathering information.

BIOTECHNOLOGY

Under the current law (42 USC 241), the Secretary is authorized to advance research, investigations and demonstration projects in the intent of public health by initiating and supporting appropriate activities. Such activities may include the delivery of grants-in-aid to public or private institutions, acquisition of expert advice from national and international authorities, dissemination of knowledge and information through various communications channels, and the distribution of research facilities to public health officials and scientists.

In its Plan for Action II (1987), the FDA suggests ways to increase cooperation between the public and private sectors in conducting biotechnology research. One way is for the FDA to set up one or more research centers which would provide facilities and equipment for individuals or firms to test their procedures on a large scale. The efficiency of a processing method then can be confirmed before a firm commits itself to a large investment in equipment.

REGULATORY REVIEW MEDICINE TRAINING GRANTS

The FDA is experiencing some difficulty in recruiting and retaining health professionals with knowledge of regulatory affairs to support the agency's rapidly expanding needs. Much of this difficulty is attributed to competition from the private sector.

The FDA's Office of Regulatory Affairs heads the agency's decentralized training program. Employees participate in courses provided by in-house staff as well as receive financial support for courses taught by local academic institutions. The current Education and Training Staff are responsible for coordinating national training programs at the agency. They provide much basic training, and some advanced courses in the areas of administration, compliance, consumer affairs, data processing, Federal-State relations, investigations, management, and analytical methods. This on-the-job training consists of short courses, seminars and workshops, and may satisfy some of the agency's on-the-job scientific, legal, regulatory and technical needs.

The Public Health Service's Parklawn Training Center provides training in office operations for support, secretarial and clerical personnel. The Commissioner's Advancement Program (CAP) is another training program, implemented during the FDA's Plan for Action (1985). This program is designed to train employees by providing on-the-job rotational assignments, career enrichment opportunities, and continuing education incentives. The CAP goals are

consistent with the agency's goals to improve internal management.

Although grants for training and educating personnel exist for such progams as the National Health Service corps, the National Advisory Council on Education for Health Professions, and the National Advisory Council on Regional Medical Programs, there is no provision for appointing highly qualified scientists within the FDA to do biomedical and clinical research.

The Department of Scientific Investigations (DSI) of the FDA's Center for Drugs and Biologics, Office of Compliance, is responsible for monitoring research facilities and clinical investigators suspected of conducting questionable research. In its report to Congress "Resources for Division of Scientific Investigations Have Been Reduced," the General Accounting Office (GAO) indicated that while research monitoring activities increased, the FDA's Division of Scientific Investigations staff has decreased from 37 to 30, or about 19 percent, between fiscal years 1981 and 1986. Travel expenditures within DSI were reduced by 28% between fiscal years 1983 and 1986. The total number of headquarters field inspections decreased by over 25 percent in 1986.

To meet the additional demands requiring regulatory review expertise, the FDA enters contracts with scientists outside the agency. These consultants are sought to advise the agency on the latest laboratory techniques and research methods. The FDA notes the the full-time employment of such experts would be costly.

SCIENTIFIC REVIEW GROUPS

The Federal Advisory Committee Act (92–463) established functions and responsibilities for those groups organized to advise officers in executive agencies. Currently, members of scientific review groups at the Food and Drug Administration are recommended by the Commissioner and must be approved by the Secretary. In addition, these scientific review groups are governed by the administrative and fiscal provisions of the Federal Advisory Committee Act. Under the proposed legislation, the Commissioner of the FDA would be responsible for administrative and fiscal duties for the scientific groups, and the scientific groups would be exempt from provisions of the Federal Advisory Committee.

III TEXT OF THE BILL AS REPORTED

Calendar No. _____

100TH CONGRESS
2D SESSION

S. 2468

[Report No. 100-____]

IN THE SENATE OF THE UNITED STATES

JUNE 6 (legislative day, MAY 18), 1988

Mr. HATCH introduced the following bill; which was read twice and referred to the Committee on Labor and Human Resources

JULY ____ (legislative day, _____), 1988

Reported by Mr. KENNEDY, with an amendment

[Strike out all after the enacting clause and insert the part printed in italic]

A BILL

To revitalize the Food and Drug Administration, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

TITLE I—REAL PROPERTY

SEC. 101. AUTHORITIES REQUIRED BY THE FOOD AND DRUG ADMINISTRATION REGARDING REAL PROPERTY, BUILDINGS, AND FACILITIES.

Chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371 et seq.) is amended by adding at the end thereof the following new section:

"SEC. 710. AUTHORITIES REQUIRED BY THE FOOD AND DRUG ADMINISTRATION REGARDING REAL PROPERTY, BUILDINGS, AND FACILITIES.

"The Secretary shall have the following general powers in connection with real property, buildings, and facilities—

"(1) to acquire, in any lawful manner, such personal or real property, or any interest in such property, as the Secretary determines necessary or convenient in the transaction of the business of the Food and Drug Administration;

"(2) to hold, maintain, sell, lease, or otherwise dispose of property acquired under paragraph (1), or any interest in such property, and to provide services in connection with such property and charges for the use of such property, when appropriate;

"(3) to design, construct, operate, lease, and maintain buildings, facilities, equipment, and other

improvements on any property owned or controlled by the Food and Drug Administration, including, without limitation, any property or interest therein transferred to the Administration under any other paragraph;

''(4) to acquire buildings, facilities, equipment, and make other improvements on any property owned, acquired, or controlled by the Food and Drug Administration through the use of lease-purchase or lease-construction contracts, when and as appropriate; and

''(5) to accept gifts or donations of services or property, real or personal, as the Secretary determines necessary in the transaction of the business of the Food and Drug Administration.

TITLE II—SENIOR BIOMEDICAL SCIENTIFIC SERVICE

SEC. 201. BIOMEDICAL RESEARCH.

Part A of title III of the Public Health Service Act is amended by inserting after section 301 (42 U.S.C. 241) the following new section:

"SEC. 301A. BIOMEDICAL SCIENTIFIC SERVICE.

''(a) ESTABLISHMENT.—The Secretary is authorized to establish a Senior Biomedical Scientific Service (hereinafter in this section referred to as the 'Service').

~~"(b) MEMBERSHIP.—~~

~~"(1) CIVIL SERVICE.—Individuals chosen to serve in the Service shall not be a part of the competitive service established under chapter 33 of subpart B of part I of title 5, United States Code.~~

~~"(2) APPOINTMENT.—A person may be appointed to the Service by the Secretary based solely on that person's distinction and achievement in the fields of biomedical research or clinical research evaluation.~~

~~"(c) DUTIES.—Members of the Service shall be assigned to duties that require expertise in biomedical research, behavioral research, or clinical research evaluation, and may also be assigned to supervise other scientists in carrying out the activities described in this subsection.~~

~~"(d) COMPENSATION.—Individuals selected to serve on the Service staff by the Secretary under subsection (b), shall be compensated at a rate not in excess of 110 percent of the annual rate of pay in effect for level I of the Executive Salary Schedule established in section 5512 of title 5, United States Code.~~

~~"(e) RETIREMENT.—For purposes of section 211, the continuous service in the Service of any person who commences such service on termination of service as a commissioned officer in the Public Health Service Corps may~~

be treated as service as a commissioned officer in the Public Health Service Corps and shall not be considered as service that is subject to any other retirement system for officers and employees of the Federal Government.''.

TITLE III—INCREASED FTE AUTHORITY FOR STAFF

SEC. 301. INCREASED FTE AUTHORITY FOR STAFF.

Notwithstanding any other provision of law, the Secretary of Health and Human Services, through the Commissioner of Food and Drugs, may, in accordance with the civil service and classification laws, appoint and fix the compensation of not more than 350 employees for the Food and Drug Administration in addition to the number of employees assigned to such Administration as of July 1, 1987.

TITLE IV—SMALL BUSINESS TRAINING AND TECHNICAL ASSISTANCE

Section 10 of the Medical Device Amendments of 1976 (42 U.S.C. 3512) is amended—

(1) by inserting ''(a)'' after the section designation; and

(2) by adding at the end thereof the following new subsection:

''(b) There are authorized to be appropriated to carry out the provisions of this section, $18,000,000 in each of the fiscal years 1989 through 1991.''.

TITLE V—BIOTECHNOLOGY

Chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371 et seq.) (as amended by section 101), is further amended by adding at the end thereof the following new section:

"SEC. 711. USE OF FACILITIES.

''(a) IN GENERAL.—The Secretary shall establish and implement a demonstration project that authorizes the Secretary to use the facilities of any public or private cooperative, with the permission of any such cooperative, to perform any of the activities authorized under this Act.

''(b) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section, $10,000,000 in fiscal year 1989, and such sums as are necessary in each of the fiscal years 1990 and 1991.

''(c) REGULATIONS.—The Secretary shall promulgate regulations necessary to carry out this section.''.

TITLE VI—NEGLIGIBLE RISK

SEC. 601. NEGLIGIBLE RISK FOR FOOD ADDITIVES.

Section 409(c)(3)(A) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 348(c)(3)(A)) is amended by striking out '': *Provided*, That no additive'' and all that

follows through the end of such subparagraph, and inserting in lieu thereof the following:

"; except that no additive shall be deemed to be safe if the additive as a whole is found to induce cancer when ingested by man or animal, or if the additive as a whole is found, after tests that are appropriate for the evaluation of the safety of food additives, to induce cancer in man or animal, except that the foregoing provisions of this paragraph shall not apply with respect to a use of an additive if the Secretary, on the basis of a petition containing scientifically adequate evidence with respect to the mechanism of action of the additive or the manner in which the additive is metabolized, or other adequate evidence, including the use of risk assessment procedures when appropriate, determines that the risk of cancer to humans from exposure to the additive under the intended conditions of such use is negligible; or".

SEC. 602. NEGLIGIBLE RISK FOR ANIMAL DRUGS.

Section 512(d)(1)(H) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(d)(1)(H)) is amended to read as follows:

"(H) such drug as a whole is found to induce cancer when ingested by man or animal, or if the

drug as a whole is found, after tests that are appropriate for the evaluation of the safety of animal drugs, to induce cancer in man or animal, except that the foregoing provisions of this paragraph shall not apply with respect to the use of a drug if the Secretary, on the basis of an application containing scientifically adequate evidence with respect to the mechanism of action of the drug or the manner in which the drug is metabolized, or other adequate evidence, including the use of risk assessment procedures when appropriate, determines that the risk of cancer to humans from exposure to the drug under the intended conditions of such use is negligible;''.

SEC. 603. NEGLIGIBLE RISK FOR COLOR ADDITIVES.

Section 706(b)(5)(B) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 376(b)(5)(B)) is amended to read as follows:

''(B) A color additive shall be deemed unsafe, and shall not be listed, for any use which—

''(i) will or may result in ingestion of all or part of such additive, if the additive as a whole is found to induce cancer when ingested by man or animal, or if the additive as a whole is found, after tests that are appropriate for the evaluation of the safety of

color additives, to induce cancer in man or animal; or

"(ii) will not result in ingestion of any part of such additive, if, after tests that are appropriate for the evaluation of the safety of color additives for such use, or after other relevant exposure of man or animal to such additive, the additive as a whole is found to induce cancer in man or animal;

except that the provisions of this subparagraph shall not apply with respect to a use of an additive if the Secretary, on the basis of a petition containing scientifically adequate evidence with respect to the mechanism of action of the additive or the manner in which the additive is metabolized, or other adequate evidence, including the use of risk assessment procedures when appropriate, determines that the risk of cancer to humans from exposure to the additive under the intended conditions of such use is negligible.".

TITLE VII—UNIFORMITY IN REGULATION

SEC. 701. UNIFORMITY IN REGULATION.

Chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 701 et seq.) (as amended by sections 101 and 501), is further amended by adding at the end thereof the following new section:

"SEC. 712. NATIONAL UNIFORMITY IN REGULATION.

"(a) INTENT OF CONGRESS.—It is the intent of Congress to require national uniformity in all aspects of the regulation of food for human use, drugs, devices, and cosmetics in order to—

"(1) prevent interference with the objectives and purposes of Federal regulations;

"(2) to assure the primary jurisdiction of the Food and Drug Administration in protecting the public health with respect to such articles; and

"(3) to permit national marketing of such articles without jurisdictional barriers.

"(b) FEDERAL EFFECT ON STATE REQUIREMENTS.—

"(1) GENERAL RULE.—No State or political subdivision of a State shall establish or continue in effect any requirement relating to the regulation of a food for human use, drug, device, or cosmetic unless such a requirement is also established pursuant to a statute for which responsibility for the administration or implementation has been delegated by law or by the Secretary to the Commissioner of Food and Drugs, and the State or local requirement is identical to the Federal requirement, except as otherwise provided for in this section.

"(2) DEFINITION.—As used in this section, the term 'requirement relating to the regulation of a food

for human use, drug, device, or cosmetic' shall include—

"(A) any requirement or prohibition relating to the subject matter in any provision of any of the statutes described in paragraph (1); or

"(B) any requirement relating to the dissemination of information about a food for human use, drug, device, or cosmetic in any manner, such as by posters, public notices, advertising, or other means of communication.

"(e) CONCURRENT JURISDICTION.—Any State or political subdivision of a State may exercise concurrent jurisdiction with the Secretary over the regulation of a food for human use, drug, device, or cosmetic for the purpose of enforcing any requirement that is identical to a requirement established pursuant to the provisions of any of the statutes described in paragraph (1), or the administrative implementation thereunder.

"(d) EXEMPTION.—On application of a State or political subdivision of a State, the Secretary may by regulation, after notice and opportunity for written and oral presentation of views, exempt a proposed requirement relating to the regulation of a food for human use, drug, device, or cosmetic described in such application from the provisions

of paragraph (b) under such conditions as the Secretary may impose, if the proposed requirement—

''(1) is justified by compelling and unique local conditions that do not exist elsewhere in the United States; or

''(2)(A) protects an important public interest that would otherwise be unprotected;

''(B) relates to a subject matter that is primarily local in nature and the Federal agency with responsibility over such is not exercising jurisdiction over the requirement;

''(C) would not cause any food, drug, device, or cosmetic to be in violation of any applicable requirement under Federal law; and

''(D) would not unduly burden interstate commerce.

''(c) PETITION FOR REGULATION.—A State or political subdivision of a State may petition the Secretary for the adoption, by regulation, of an existing or proposed State or local requirement relating to the regulation of a food, drug, device, or cosmetic as a Federal requirement.''.

~~TITLE VIII—REGULATORY REVIEW MEDICINE TRAINING GRANTS~~

~~SEC. 801. REGULATORY REVIEW MEDICINE TRAINING GRANTS.~~

~~The Federal Food, Drug, and Cosmetic Act is amended by adding after subtitle IX (21 U.S.C. 391 et seq.) the following new subtitle:~~

~~"CHAPTER X—TRAINING GRANTS AND LOAN REPAYMENT~~

~~"Subchapter A—Regulatory Review Medicine Training Grants~~

~~"SEC. 1001. AUTHORITY.~~

~~"The Secretary may make grants to, or enter into contracts with, any public or nonprofit academic institution, including schools of medicine, dentistry, and pharmacy to enable such institutions to design and develop core curriculum programs that will be used to train individuals in the field of regulatory review medicine.~~

~~"SEC. 1002. REQUIREMENTS.~~

~~"(a) IN GENERAL.—No grant shall be awarded under this subchapter unless—~~

~~"(1) the institution has submitted to the Secretary an application for a grant and the Secretary has approved the application; and~~

~~"(2) the institution provides, in such form and manner as the Secretary shall by regulation pre-~~

scribe, assurances satisfactory to the Secretary that individuals receiving funds through the institution under such grants will meet the service requirement of section 1004.

''(b) APPLICATION.—An application for a grant submitted under subsection (a) shall be in such form, submitted in such manner, and contain such information, as the Secretary may by regulation prescribe.

''SEC. 1003. USE OF GRANTS.

''An institution that receives a grant under this subchapter—

''(1) shall use such grant to—

''(A) design and develop a core curriculum program that has as its primary emphasis regulatory review medicine; and

''(B) train health professionals and scientists in regulatory review medicine; and

''(2) may use such grant to provide stipends, tuition, fees, and allowances (including travel and subsistence expenses and dependency allowances), to individuals who participate in the regulatory review medicine program developed with funds provided under this subchapter.

"SEC. 1004. REQUIREMENT OF SERVICE.

"(a) IN GENERAL.—Each individual who receives funds from an institution through a grant provided under this subchapter shall, in accordance with subsection (c), serve an obligated period of time as an employee of the Food and Drug Administration.

"(b) PERIOD OF REQUIRED SERVICE.—For each month for which an individual receives funds in accordance with subsection (a), such individual shall remain employed for two months with the Food and Drug Administration.

"(c) COMPLIANCE.—The requirements of this section shall be complied with by any individual to whom it applies within such reasonable period of time, after the completion of such individual's training under the grant received under this subchapter, as the Secretary shall by regulation prescribe.

"(d) FAILURE TO COMPLY.—If any individual to whom this section applies fails, within the period prescribed under subsection (c), to comply with such requirements, the United States shall be entitled to recover from such individual an amount determined in accordance with a formula prescribed through regulations issued by the Secretary.

"SEC. 1005. AUTHORIZATION OF APPROPRIATIONS.

"There are authorized to be appropriated to make grants under this subchapter $4,000,000 for fiscal year

1989, and such sums as may be necessary for each of the fiscal years 1990 through 1991.''.

SEC. 802. SCIENCE TRAINING GRANT LOAN REPAYMENT PROGRAM.

Chapter X of the Federal Food, Drug, and Cosmetic Act (as added by section 801 of this Act) is amended by adding at the end thereof the following new subchapter:

''Subchapter B—Science Training Grant Loan Repayment Program

''SEC. 1010. SCIENCE TRAINING GRANT LOAN REPAYMENT PROGRAM.

''(a) ESTABLISHMENT.—The Secretary shall establish a program to be known as the Science Training Grant Loan Repayment Program (hereinafter in this subpart referred to as the 'Loan Repayment Program') in order to assure—

''(1) an adequate supply of trained physicians, dentists, and pharmacists; and

''(2) an adequate supply of veterinarians and other health professionals as determined to be necessary from time to time by the Secretary.

''(b) ELIGIBILITY.—To be eligible to participate in the Loan Repayment Program, an individual must—

''(1)(A) be enrolled—

''(i) as a full-time student in an accredited educational institution in a State; or

~~"(ii) in a training program in regulatory review medicine as described in regulations issued by the Secretary; or~~

~~"(B) have—~~

~~"(i) a degree in medicine, osteopathy, dentistry, or other health profession; and~~

~~"(ii) completed an approved graduate training program in regulatory review medicine, except that the Secretary may waive the completion requirement of this clause for good cause;~~

~~"(2) be eligible for employment with the Food and Drug Administration;~~

~~"(3) submit an application to participate in the Loan Repayment Program; and~~

~~"(4) sign and submit to the Secretary, at the time of the submission of such application, a written contract (described in subsection (f)) to accept repayment of educational loans and to serve (in accordance with this subtitle) for the applicable period of obligated service with the Food and Drug Administration.~~

~~"(c) APPLICATION, CONTRACT, AND INFORMATION REQUIREMENTS.—~~

"(1) SUMMARY AND INFORMATION.—In disseminating application forms and contract forms to individuals desiring to participate in the Loan Repayment Program, the Secretary shall include with such forms—

"(A) a fair summary of the rights and liabilities of an individual whose application is approved (and whose contract is accepted) by the Secretary, including in the summary a clear explanation of the damages to which the United States is entitled under section 1012 in the case of the individual's breach of the contract; and

"(B) such other information as may be necessary for the individual to understand the individual's prospective participation in the Loan Repayment Program.

"(2) UNDERSTANDABILITY.—The application form, contract form, and all other information furnished by the Secretary under this subtitle shall be written in a manner calculated to be understood by the average individual applying to participate in the Loan Repayment Program.

"(3) AVAILABILITY.—The Secretary shall make such application forms, contract forms, and other in-

formation available to individuals desiring to participate in the Loan Repayment Program.

''(d) PRIORITY.—In determining which applications under the Loan Repayment Program to approve (and which contracts to accept), the Secretary shall give priority to applications made by—

''(1) individuals whose training is in regulatory review medicine and in a health profession or specialty determined by the Secretary to be needed; and

''(2) individuals who are committed to service with the Food and Drug Administration.

''(e) APPROVAL REQUIRED FOR PARTICIPATION.—

''(1) IN GENERAL.—An individual becomes a participant in the Loan Repayment Program only on the Secretary's approval of the individual's application submitted under subsection (b)(3) and the Secretary's acceptance of the contract submitted by the individual under subsection (b)(4).

''(2) WRITTEN NOTICE.—The Secretary shall provide written notice to an individual promptly on—

''(A) the Secretary's approving, under paragraph (1), the individual's participation in the Loan Repayment Program; or

"(B) the Secretary's disapproving the individual's participation in such Program.

"(f) CONTENTS OF CONTRACTS.—The written contract (referred to in this subchapter) between the Secretary and an individual shall contain—

"(1) an agreement that—

"(A) subject to paragraph (3), the Secretary agrees—

"(i) to pay on behalf of the individual loans in accordance with subsection (g); and

"(ii) to accept (subject to the availability of appropriated funds for carrying out this subchapter) the individual as being qualified for employment with the Food and Drug Administration; and

"(B) subject to paragraph (3), the individual agrees—

"(i) to accept loan payments on behalf of the individual;

"(ii) in the case of an individual described in subsection (b)(1)(A), to maintain enrollment in a course of study or training described in such subsection until the indi-

vidual completes the course of study or training;

"(iii) in the case of an individual described in subsection (b)(1)(A), while enrolled in such course of study or training, to maintain an acceptable level of academic standing (as determined under regulations of the Secretary by the educational institution offering such course of study or training); and

"(iv) to serve for a time period (hereinafter in this subchapter referred to as the 'period of obligated service') for a period of time described in regulations issued by the Secretary or such longer period as the individual may agree to, with the Food and Drug Administration;

"(2) a provision permitting the Secretary to extend for such longer additional periods, as the individual may agree to, the period of obligated service agreed to by the individual under paragraph (1)(B)(iv);

"(3) a provision that any financial obligation of the United States arising out of a contract entered into under this subtitle and any obligation of the in-

dividual that is conditioned thereon, is contingent on funds being appropriated for loan repayments under this subtitle;

"(4) a statement of the damages to which the United States is entitled, under section 1012, for the individual's breach of the contract; and

"(5) such other statements of the rights and liabilities of the Secretary and of the individual, not inconsistent with this subpart.

"(g) PAYMENTS.—

"(1) IN GENERAL.—A loan repayment provided for an individual under a written contract under the Loan Repayment Program shall consist of payment, in accordance with paragraph (2), on behalf of the individual of the principal, interest, and related expenses on government and commercial loans received by the individual for—

"(A) tuition expenses;

"(B) all other reasonable educational expenses, including fees, books, and laboratory expenses, incurred by the individual; or

"(C) reasonable living expenses as determined by the Secretary.

"(2) PAYMENTS FOR YEARS SERVED.—

"(A) IN GENERAL.—Except as provided in paragraph (3), for each year of obligated service that an individual contracts to serve under subsection (f) the Secretary may pay up to $20,000 on behalf of the individual for loans described in paragraph (1).

"(B) REPAYMENT SCHEDULE.—Any arrangement made by the Secretary for the making of loan repayments in accordance with this subsection shall provide that any repayments for a year of obligated service shall be made no later than the end of the fiscal year in which the individual completes such year of service.

"(3) TAX LIABILITY.—In addition to payments made under paragraph (2), in any case in which payments on behalf of an individual under the Loan Repayment Program result in an increase in Federal, State, or local income tax liability for such individual, the Secretary may, on the request of such individual, make payments to such individual in a reasonable amount, as determined by the Secretary, to reimburse such individual for all or part of the increased tax liability of the individual.

"(4) PAYMENT SCHEDULE.—The Secretary may enter into an agreement with the holder of any loan

for which payments are made under the Loan Repayment Program to establish a schedule for the making of such payments.

''(h) EMPLOYMENT CEILING.—Notwithstanding any other provision of law, individuals who have entered into written contracts with the Secretary under this section, while undergoing academic or other training, shall not be counted against any employment ceiling affecting the Department.

''(i) REPORTS.—The Secretary shall, not later than March 1 of each year, submit to the Congress a report specifying—

''(1) the number, and type of health profession training, of individuals receiving loan payments under the Loan Repayment Program;

''(2) the educational institution at which such individuals are receiving their training;

''(3) the number of applications filed under this section in the school year beginning in such year and in prior school years; and

''(4) the amount of loan payments made in the year reported on.

"SEC. 1011. OBLIGATED SERVICE.

''(a) GENERAL RULE.—Each individual who has entered into a written contract with the Secretary under sec-

tion 1010 shall provide service as a full-time employee of the Food and Drug Administration for the period of obligated service provided in such contract.

''(b) PROCEDURE FOR SERVICE.—

''(1) DETERMINATION OF SERVICE.—If an individual is required under subsection (a) to provide service as specified in section 1010(f)(1)(B)(iv) (hereinafter in this subsection referred to as 'obligated service'), the Secretary shall, not later than 90 days before the date described in paragraph (4), determine if the individual shall provide such service as a member of the Commissioner Corps of the Public Health Service or a civilian employee of the United States.

''(2) INFORMATION AND NOTIFICATION.—

''(A) PROVISION OF INFORMATION.—If the Secretary determines that an individual shall provide obligated service as a Commissioned Officer, or a civilian employee of the United States, the Secretary shall, not later than 60 days before the date described in paragraph (4), provide such individual with sufficient information regarding the advantages and disadvantages of service as such a commissioned officer or ci-

vilian employee to enable the individual to make a decision on an informed basis.

"(B) NOTIFICATION.—To be eligible to provide obligated service as a Commissioned Officer, an individual shall notify the Secretary, not later than 30 days before the date described in paragraph (4), of the individual's desire to provide such service as such an officer.

"(3) CIVILIAN EMPLOYEES.—If an individual provided notice by the Secretary under paragraph (2) does not qualify for appointment as a Commissioned Officer, the Secretary shall, as soon as possible after the date described in paragraph (4), appoint such individual as a civilian employee of the United States.

"(4) NOTIFICATION DATE.—In the case of the Loan Repayment Program, if an individual is required to provide obligated service under such Program, the date referred to in paragraphs (1) through (3)—

"(A) shall, in the case of an individual who is enrolled in an approved training program in regulatory review medicine, be the date the individual completes such training program; or

"(B) shall be the date the individual enters into an agreement with the Secretary under section 1010.

"(c) BEGINNING OF SERVICE.—An individual shall be considered to have begun serving a period of obligated service on the date such individual is appointed as either a Commissioned Officer or a civilian employee of the United States.

"SEC. 1012. BREACH OF CONTRACT.

"The Secretary shall by regulation establish the penalties applicable to an individual that breaches the contract entered into under section 1010 by failing (for any reason) to begin his service obligation in accordance with an agreement entered into under section 1011, or to complete such service obligation.

"SEC. 1013. TRANSPORTATION EXPENSES.

"The Secretary may pay an individual who has entered into an agreement with the Secretary under section 1010 an amount to cover all or part of the individual's expenses reasonably incurred in transporting himself, his family, and his possessions to the location of his duty station.

"SEC. 1014. AUTHORIZATION OF APPROPRIATIONS.

"There are authorized to be appropriated to make grants under this subchapter $2,000,000 for fiscal year

1989, and such sums as may be necessary for each of the fiscal years 1990 through 1991.''.

TITLE IX—SCIENTIFIC REVIEW GROUPS

SEC. 901. SCIENTIFIC REVIEW GROUPS.

Chapter IX of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 391 et seq.) is amended by adding at the end thereof the following new section:

"SEC. 903. SCIENTIFIC REVIEW GROUPS.

''The Commissioner of Food and Drugs may, without regard to the provisions of title 5, United States Code, governing appointments in the competitive service and without regard to the provisions of chapter 51 and subchapter III of chapter 53 of such title relating to classification and General Schedule pay rates, establish such technical and scientific review groups as are needed to carry out the functions of the Administration, including functions under the Federal Food, Drug, and Cosmetic Act, and appoint and pay the members of such groups, except that officers and employees of the United States shall not receive additional compensation for service as members of such groups. The Federal Advisory Committee Act shall not apply to the duration of a peer review group appointed under this section.''

SECTION 1. SHORT TITLE.

This Act may be cited as the "FDA Revitalization Act".

TITLE I—REAL PROPERTY

SEC. 101. AUTHORITIES REQUIRED BY THE FOOD AND DRUG ADMINISTRATION REGARDING REAL PROPERTY, BUILDINGS, AND FACILITIES.

Chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371 et seq.) is amended by adding at the end thereof the following new section:

"SEC. 710. AUTHORITIES REQUIRED BY THE FOOD AND DRUG ADMINISTRATION REGARDING REAL PROPERTY, BUILDINGS, AND FACILITIES.

"The Secretary shall have the following general powers in connection with real property, buildings, and facilities—

"(1) to acquire, in any lawful manner, such personal or real property, or any interest in such property, as the Secretary determines necessary or convenient in the transaction of the business of the Food and Drug Administration;

"(2) to hold, maintain, sell, lease, or otherwise dispose of property acquired under paragraph (1), or any interest in such property, and to provide services in connection with such property and charges for the use of such property, when appropriate;

"(3) to design, construct, operate, lease, and maintain buildings, facilities, equipment, and other improvements on any property owned or controlled by the Food and Drug Administration, including, without limitation, any property or interest therein transferred to the Administration under any other paragraph;

"(4) to acquire buildings, facilities, equipment, and make other improvements on any property owned, acquired, or controlled by the Food and Drug Administration through the use of lease-purchase or lease-construction contracts, when and as appropriate; and

"(5) to accept gifts or donations of services or property, real or personal, as the Secretary determines necessary in the transaction of the business of the Food and Drug Administration.

TITLE II—SENIOR BIOMEDICAL SCIENTIFIC SERVICE

SEC. 201. BIOMEDICAL RESEARCH.

Part A of title III of the Public Health Service Act is amended by inserting after section 301 (42 U.S.C. 241) the following new section:

"SEC. 301A. BIOMEDICAL SCIENTIFIC SERVICE.

"(a) ESTABLISHMENT.—The Secretary is authorized to establish a Senior Biomedical Scientific Service (hereinafter in this section referred to as the 'Service').

"(b) MEMBERSHIP.—

"(1) CIVIL SERVICE.—Individuals chosen to serve in the Service shall not be a part of the competitive service established under chapter 33 of subpart B of part I of title 5, United States Code.

"(2) APPOINTMENT.—A person may be appointed to the Service by the Secretary based solely on that person's distinction and achievement in the fields of biomedical research or clinical research evaluation.

"(c) DUTIES.—Members of the Service shall be assigned to duties that require expertise in biomedical research, behavioral research, or clinical research evaluation, and may also be assigned to supervise other scientists in carrying out the activities described in this subsection.

"(d) COMPENSATION.—Individuals selected to serve on the Service staff by the Secretary under subsection (b), shall be compensated at a rate not in excess of 110 percent of the annual rate of pay in effect for level I of the Executive Salary Schedule established in section 5512 of title 5, United States Code.

"(e) RETIREMENT.—For purposes of section 211, the continuous service in the Service of any person who com-

mences such service on termination of service as a commissioned officer in the Public Health Service Corps may be treated as service as a commissioned officer in the Public Health Service Corps and shall not be considered as service that is subject to any other retirement system for officers and employees of the Federal Government.''.

TITLE III—INCREASED FTE AUTHORITY FOR STAFF

SEC. 301. INCREASED FTE AUTHORITY FOR STAFF.

Notwithstanding any other provision of law, the Secretary of Health and Human Services, through the Commissioner of Food and Drugs, may, in accordance with the civil service and classification laws, appoint and fix the compensation of not more than 350 employees for the Food and Drug Administration in addition to the number of employees assigned to such Administration as of July 1, 1987.

TITLE IV—SMALL BUSINESS TRAINING AND TECHNICAL ASSISTANCE

SEC. 401. SMALL BUSINESS TRAINING AND TECHNICAL ASSISTANCE.

Section 10 of the Medical Device Amendments of 1976 (42 U.S.C. 3512) is amended—

(1) by inserting ''(a)'' after the section designation; and

(2) by adding at the end thereof the following new subsection:

''(b) There are authorized to be appropriated to carry out the provisions of this section, $18,000,000 in each of the fiscal years 1989 through 1991.''.

TITLE V—BIOTECHNOLOGY

SEC. 501. BIOTECHNOLOGY.

Chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371 et seq.) (as amended by section 101), is further amended by adding at the end thereof the following new section:

"SEC. 711. USE OF FACILITIES.

''(a) IN GENERAL.—The Secretary shall establish and implement a demonstration project that authorizes the Secretary to use the facilities of any public or private cooperative, with the permission of any such cooperative, to perform any of the activities authorized under this Act.

''(b) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section, $10,000,000 in fiscal year 1989, and such sums as are necessary in each of the fiscal years 1990 and 1991.

''(c) REGULATIONS.—The Secretary shall promulgate regulations necessary to carry out this section.''.

TITLE VI—REGULATORY REVIEW MEDICINE TRAINING GRANTS

SEC. 601. REGULATORY REVIEW MEDICINE TRAINING GRANTS.

The Federal Food, Drug, and Cosmetic Act is amended by adding after subtitle IX (21 U.S.C. 391 et seq.) the following new subtitle:

''CHAPTER X—TRAINING GRANTS AND LOAN REPAYMENT

''Subchapter A—Regulatory Review Medicine Training Grants

''SEC. 1001. AUTHORITY.

''The Secretary may make grants to, or enter into contracts with, any public or nonprofit academic institution, including schools of medicine, dentistry, and pharmacy to enable such institutions to design and develop core curriculum programs that will be used to train individuals in the field of regulatory review medicine.

''SEC. 1002. REQUIREMENTS.

''(a) IN GENERAL.—No grant shall be awarded under this subchapter unless—

''(1) the institution has submitted to the Secretary an application for a grant and the Secretary has approved the application; and

''(2) the institution provides, in such form and manner as the Secretary shall by regulation pre-

scribe, assurances satisfactory to the Secretary that individuals receiving funds through the institution under such grants will meet the service requirement of section 1004.

''(b) APPLICATION.—An application for a grant submitted under subsection (a) shall be in such form, submitted in such manner, and contain such information, as the Secretary may by regulation prescribe.

''SEC. 1003. USE OF GRANTS.

''An institution that receives a grant under this subchapter—

''(1) shall use such grant to—

''(A) design and develop a core curriculum program that has as its primary emphasis regulatory review medicine; and

''(B) train health professionals and scientists in regulatory review medicine; and

''(2) may use such grant to provide stipends, tuition, fees, and allowances (including travel and subsistence expenses and dependency allowances), to individuals who participate in the regulatory review medicine program developed with funds provided under this subchapter.

"SEC. 1004. REQUIREMENT OF SERVICE.

"(a) IN GENERAL.—Each individual who receives funds from an institution through a grant provided under this subchapter shall, in accordance with subsection (c), serve an obligated period of time as an employee of the Food and Drug Administration.

"(b) PERIOD OF REQUIRED SERVICE.—For each month for which an individual receives funds in accordance with subsection (a), such individual shall remain employed for two months with the Food and Drug Administration.

"(c) COMPLIANCE.—The requirements of this section shall be complied with by any individual to whom it applies within such reasonable period of time, after the completion of such individual's training under the grant received under this subchapter, as the Secretary shall by regulation prescribe.

"(d) FAILURE TO COMPLY.—If any individual to whom this section applies fails, within the period prescribed under subsection (c), to comply with such requirements, the United States shall be entitled to recover from such individual an amount determined in accordance with a formula prescribed through regulations issued by the Secretary.

"SEC. 1005. AUTHORIZATION OF APPROPRIATIONS.

"There are authorized to be appropriated to make grants under this subchapter $4,000,000 for fiscal year

1989, and such sums as may be necessary for each of the fiscal years 1990 through 1991.''.

SEC. 602. SCIENCE TRAINING GRANT LOAN REPAYMENT PROGRAM.

Chapter X of the Federal Food, Drug, and Cosmetic Act (as added by section 601 of this Act) is amended by adding at the end thereof the following new subchapter:

''Subchapter B—Science Training Grant Loan Repayment Program

''SEC. 1010. SCIENCE TRAINING GRANT LOAN REPAYMENT PROGRAM.

''(a) ESTABLISHMENT.—The Secretary shall establish a program to be known as the Science Training Grant Loan Repayment Program (hereinafter in this subpart referred to as the 'Loan Repayment Program') in order to assure—

''(1) an adequate supply of trained physicians, dentists, and pharmacists; and

''(2) an adequate supply of veterinarians and other health professionals as determined to be necessary from time to time by the Secretary.

''(b) ELIGIBILITY.—To be eligible to participate in the Loan Repayment Program, an individual must—

''(1)(A) be enrolled—

''(i) as a full-time student in an accredited educational institution in a State; or

"(ii) in a training program in regulatory review medicine as described in regulations issued by the Secretary; or

"(B) have—

"(i) a degree in medicine, osteopathy, dentistry, or other health profession; and

"(ii) completed an approved graduate training program in regulatory review medicine, except that the Secretary may waive the completion requirement of this clause for good cause;

"(2) be eligible for employment with the Food and Drug Administration;

"(3) submit an application to participate in the Loan Repayment Program; and

"(4) sign and submit to the Secretary, at the time of the submission of such application, a written contract (described in subsection (f)) to accept repayment of educational loans and to serve (in accordance with this subtitle) for the applicable period of obligated service with the Food and Drug Administration.

"(c) APPLICATION, CONTRACT, AND INFORMATION REQUIREMENTS.—

"(1) SUMMARY AND INFORMATION.—In disseminating application forms and contract forms to individ-

uals desiring to participate in the Loan Repayment Program, the Secretary shall include with such forms—

"(A) a fair summary of the rights and liabilities of an individual whose application is approved (and whose contract is accepted) by the Secretary, including in the summary a clear explanation of the damages to which the United States is entitled under section 1012 in the case of the individual's breach of the contract; and

"(B) such other information as may be necessary for the individual to understand the individual's prospective participation in the Loan Repayment Program.

"(2) UNDERSTANDABILITY.—The application form, contract form, and all other information furnished by the Secretary under this subtitle shall be written in a manner calculated to be understood by the average individual applying to participate in the Loan Repayment Program.

"(3) AVAILABILITY.—The Secretary shall make such application forms, contract forms, and other information available to individuals desiring to participate in the Loan Repayment Program.

"(d) PRIORITY.—In determining which applications under the Loan Repayment Program to approve (and which contracts to accept), the Secretary shall give priority to applications made by—

"(1) individuals whose training is in regulatory review medicine and in a health profession or specialty determined by the Secretary to be needed; and

"(2) individuals who are committed to service with the Food and Drug Administration.

"(e) APPROVAL REQUIRED FOR PARTICIPATION.—

"(1) IN GENERAL.—An individual becomes a participant in the Loan Repayment Program only on the Secretary's approval of the individual's application submitted under subsection (b)(3) and the Secretary's acceptance of the contract submitted by the individual under subsection (b)(4).

"(2) WRITTEN NOTICE.—The Secretary shall provide written notice to an individual promptly on—

"(A) the Secretary's approving, under paragraph (1), the individual's participation in the Loan Repayment Program; or

"(B) the Secretary's disapproving the individual's participation in such Program.

''(f) CONTENTS OF CONTRACTS.—The written contract (referred to in this subchapter) between the Secretary and an individual shall contain—

''(1) an agreement that—

''(A) subject to paragraph (3), the Secretary agrees—

''(i) to pay on behalf of the individual loans in accordance with subsection (g); and

''(ii) to accept (subject to the availability of appropriated funds for carrying out this subchapter) the individual as being qualified for employment with the Food and Drug Administration; and

''(B) subject to paragraph (3), the individual agrees—

''(i) to accept loan payments on behalf of the individual;

''(ii) in the case of an individual described in subsection (b)(1)(A), to maintain enrollment in a course of study or training described in such subsection until the individual completes the course of study or training;

"(iii) in the case of an individual described in subsection (b)(1)(A), while enrolled in such course of study or training, to maintain an acceptable level of academic standing (as determined under regulations of the Secretary by the educational institution offering such course of study or training); and

"(iv) to serve for a time period (hereinafter in this subchapter referred to as the 'period of obligated service') for a period of time described in regulations issued by the Secretary or such longer period as the individual may agree to, with the Food and Drug Administration;

"(2) a provision permitting the Secretary to extend for such longer additional periods, as the individual may agree to, the period of obligated service agreed to by the individual under paragraph (1)(B)(iv);

"(3) a provision that any financial obligation of the United States arising out of a contract entered into under this subtitle and any obligation of the individual that is conditioned thereon, is contingent on

funds being appropriated for loan repayments under this subtitle;

"(4) a statement of the damages to which the United States is entitled, under section 1012, for the individual's breach of the contract; and

"(5) such other statements of the rights and liabilities of the Secretary and of the individual, not inconsistent with this subpart.

"(g) PAYMENTS.—

"(1) IN GENERAL.—A loan repayment provided for an individual under a written contract under the Loan Repayment Program shall consist of payment, in accordance with paragraph (2), on behalf of the individual of the principal, interest, and related expenses on government and commercial loans received by the individual for—

"(A) tuition expenses;

"(B) all other reasonable educational expenses, including fees, books, and laboratory expenses, incurred by the individual; or

"(C) reasonable living expenses as determined by the Secretary.

"(2) PAYMENTS FOR YEARS SERVED.—

"(A) IN GENERAL.—Except as provided in paragraph (3), for each year of obligated serv-

ice that an individual contracts to serve under subsection (f) the Secretary may pay up to $20,000 on behalf of the individual for loans described in paragraph (1).

"(B) REPAYMENT SCHEDULE.—Any arrangement made by the Secretary for the making of loan repayments in accordance with this subsection shall provide that any repayments for a year of obligated service shall be made no later than the end of the fiscal year in which the individual completes such year of service.

"(3) TAX LIABILITY.—In addition to payments made under paragraph (2), in any case in which payments on behalf of an individual under the Loan Repayment Program result in an increase in Federal, State, or local income tax liability for such individual, the Secretary may, on the request of such individual, make payments to such individual in a reasonable amount, as determined by the Secretary, to reimburse such individual for all or part of the increased tax liability of the individual.

"(4) PAYMENT SCHEDULE.—The Secretary may enter into an agreement with the holder of any loan for which payments are made under the Loan Repay-

ment Program to establish a schedule for the making of such payments.

''(h) EMPLOYMENT CEILING.—Notwithstanding any other provision of law, individuals who have entered into written contracts with the Secretary under this section, while undergoing academic or other training, shall not be counted against any employment ceiling affecting the Department.

''(i) REPORTS.—The Secretary shall, not later than March 1 of each year, submit to the Congress a report specifying—

''(1) the number, and type of health profession training, of individuals receiving loan payments under the Loan Repayment Program;

''(2) the educational institution at which such individuals are receiving their training;

''(3) the number of applications filed under this section in the school year beginning in such year and in prior school years; and

''(4) the amount of loan payments made in the year reported on.

''SEC. 1011. OBLIGATED SERVICE.

''(a) GENERAL RULE.—Each individual who has entered into a written contract with the Secretary under section 1010 shall provide service as a full-time employee of

the Food and Drug Administration for the period of obligated service provided in such contract.

''(b) PROCEDURE FOR SERVICE.—

''(1) DETERMINATION OF SERVICE.—If an individual is required under subsection (a) to provide service as specified in section 1010(f)(1)(B)(iv) (hereinafter in this subsection referred to as 'obligated service'), the Secretary shall, not later than 90 days before the date described in paragraph (4), determine if the individual shall provide such service as a member of the Commissioner Corps of the Public Health Service or a civilian employee of the United States.

''(2) INFORMATION AND NOTIFICATION.—

''(A) PROVISION OF INFORMATION.—If the Secretary determines that an individual shall provide obligated service as a Commissioned Officer, or a civilian employee of the United States, the Secretary shall, not later than 60 days before the date described in paragraph (4), provide such individual with sufficient information regarding the advantages and disadvantages of service as such a commissioned officer or civilian employee to enable the individual to make a decision on an informed basis.

"(B) NOTIFICATION.—To be eligible to provide obligated service as a Commissioned Officer, an individual shall notify the Secretary, not later than 30 days before the date described in paragraph (4), of the individual's desire to provide such service as such an officer.

"(3) CIVILIAN EMPLOYEES.—If an individual provided notice by the Secretary under paragraph (2) does not qualify for appointment as a Commissioned Officer, the Secretary shall, as soon as possible after the date described in paragraph (4), appoint such individual as a civilian employee of the United States.

"(4) NOTIFICATION DATE.—In the case of the Loan Repayment Program, if an individual is required to provide obligated service under such Program, the date referred to in paragraphs (1) through (3)—

"(A) shall, in the case of an individual who is enrolled in an approved training program in regulatory review medicine, be the date the individual completes such training program; or

"(B) shall be the date the individual enters into an agreement with the Secretary under section 1010.

''(c) BEGINNING OF SERVICE.—An individual shall be considered to have begun serving a period of obligated service on the date such individual is appointed as either a Commissioned Officer or a civilian employee of the United States.

"SEC. 1012. BREACH OF CONTRACT.

''The Secretary shall by regulation establish the penalties applicable to an individual that breaches the contract entered into under section 1010 by failing (for any reason) to begin his service obligation in accordance with an agreement entered into under section 1011, or to complete such service obligation.

"SEC. 1013. TRANSPORTATION EXPENSES.

''The Secretary may pay an individual who has entered into an agreement with the Secretary under section 1010 an amount to cover all or part of the individual's expenses reasonably incurred in transporting himself, his family, and his possessions to the location of his duty station.

"SEC. 1014. AUTHORIZATION OF APPROPRIATIONS.

''There are authorized to be appropriated to make grants under this subchapter $2,000,000 for fiscal year 1989, and such sums as may be necessary for each of the fiscal years 1990 through 1991.''.

TITLE VII—SCIENTIFIC REVIEW GROUPS

SEC. 701. SCIENTIFIC REVIEW GROUPS.

Chapter IX of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 391 et seq.) is amended by adding at the end thereof the following new section:

"SEC. 903. SCIENTIFIC REVIEW GROUPS.

"The Commissioner of Food and Drugs may, without regard to the provisions of title 5, United States Code, governing appointments in the competitive service and without regard to the provisions of chapter 51 and subchapter III of chapter 53 of such title relating to classification and General Schedule pay rates, establish such technical and scientific review groups as are needed to carry out the functions of the Administration, including functions under the Federal Food, Drug, and Cosmetic Act, and appoint and pay the members of such groups, except that officers and employees of the United States shall not receive additional compensation for service as members of such groups. The Federal Advisory Committee Act shall not apply to the duration of a peer review group appointed under this section."

IV. Committee Views

The Committee strongly supports efforts to enhance the Food and Drug Administration to ensure that they continue to have the resources necessary to provide consumer protection and technology development of new foods, drugs, devices, and cosmetics. While the Food, Drug, and Cosmetic Act of 1938 continues to serve as the basic law which establishes the FDA's authority and responsibilities, the role of the agency has evolved since that time.

Today, FDA has the responsibility for regulating more than $700 billion worth of goods sold annually to Americans—constituting about 25 percent of the total expenditures for personal consumption in the United States each year. FDA must accomplish its vast and complex tasks with very limited resources—7,000 full time employees nationwide and an annual budget of only $478 million. For these reasons, the Committee supports S. 2468 which provides additional resources, both financially and legislatively, to allow FDA to continue its efforts into the 21st century.

TITLE I—REAL PROPERTY

Section 101 of Title I amends Chapter VII of the Federal Food, Drug, and Cosmetic Act by adding authority for the FDA to acquire, manage, dispose of, make improvements to and acquire property to carry out the mission of the FDA.

Currently, the FDA has staff in about 1.3 million square feet of space rented throughout the Washington metropolitan area. FDA headquarter employees are located in 23 different buildings on seven different sites in the Washington area from the District of Columbia to Silver Spring and from Beltsville to Rockville. Furthermore, some of those buildings, like the Center for Food Safety and Applied Nutrition's laboratory facilities, are inadequate and outmoded. This building, which was last remodeled over 25 years ago, has difficulty meeting the Agency's own standards for good laboratory practices.

The Committee believes that this current fragmentation of FDA personnel and the continued reliance on outmoded laboratory facilites has delayed the timely and effective handling of many time sensitive and emergency matters. This current situation has contributed to increase timeframes for product review of premarket applications of drugs, biological products, food additives, and medical devices. The current widespread scattering of FDA personnel has resulted in inefficiencies beyond the control of the Agency's senior management. The physical separation of facilities has unduly increased travel time and inhibited the exchange of ideas, information, and scienfitic expertise among FDA scientists. This exchange of ideas is crucial if the FDA is to undertake successfully its mission to protect the public health. For example, many FDA regulatory issues, like health fraud, orphan products, involve all FDA centers rather than one or two individual program areas.

Historically the FDA has had difficulty in obtaining and maintaining adequate facilities due to lack of funding for new construction and replacement of outdated facilities. The Agency has also been hampered by onerous bureaucratic procedures that have prevented it from directly acquiring new facilities. The Committee be-

lieves that consolidation of Agency facilities will help to establish FDA as a major research and biomedical institution. Consolidation will also result in greater productivity and will enable FDA scientific reviewers and researchers to communicate more easily with regulatory staff and administrators in order to ensure a uniform approach to problem solving.

The Committee believes that providing FDA with the authority to acquire property directly will expedite the Agency's ability to purchase state of the art facilities specifically designed for AIDS and biotechnology activities. The Agency's workload is growing rapidly in this area and is expected to increase greatly in the future. Present outdated laboratory facilities have hampered the FDA's ability to respond more quickly to public health priorities such as AIDS. The Committee believes that given the importance of its mission to protect the public health, the FDA needs to be consolidated in a building that contains state of the art equipment. The Committee believes that enactment of Title I of S. 2468 will enable FDA reviewers and researchers to gain greater access to modern scientific facilities and respond to rapidly advancing AIDS technology.

TITLE II—SENIOR BIOMEDICAL SCIENTIFIC SERVICE

The Committee supports the establishment of a Senior Biomedical Scientific Service outside of the competitive civil service. The members of the service would be appointed based on the distinction and achievement in biomedical research, clinical research evaluation and behavioral research. The Service would be comprised of a limited number of individuals in the Public Health Service who would be assigned to biomedical research, behavioral research, or clinical research evaluation. In addition, individuals in this Service may also be assigned to supervise other scientists involved in such research.

The members of the Service would be compensated at a rate not to exceed 110 percent of the annual rate of pay in effect for level I of the Executive Salary Schedule, as described in section 5512 of title 5, USC.

The Committee's decision to support the establishment of the service is an outgrowth of concern that salary caps are causing severe problems in recruiting and retaining top scientists in the Public Health Service. The Committee feels that the service is necessary to maintain the national and international leadership in biomedical, behavioral and clinical research in the PHS. The Senior Biomedical Service would be available for senior scientists at the Alcohol, Drug Abuse, and Mental Health Administration, the Centers for Disease Control, the Food and Drug Administration, and the National Institutes of Health.

TITLE III—INCREASED FTE AUTHORITY FOR STAFF

The Committee supports an increase in full-time equivalent staff by a minimum level of 350 employees. Such employees would be added in accordance with the civil service and classification laws.

The Committee recognizes the increased burdens placed upon the current employees at FDA to expedite the drug approval process,

especially in light AIDS, and to continue providing Americans with consumer protection. In order to do this, the FDA needs, at a minimum, 350 new full-time employees.

TITLE IV—SMALL BUSINESS TRAINING AND TECHNICAL ASSISTANCE

The Committee is aware of the special contributions that small manufacturers make to produce innovative products for the nation. In the medical device industry, the Committee has been informed that over 95% of medical device manufacturers have less than 500 employees and about 63% have less than 50 employees. To support training and technical assistance to small business, the committee supports title IV which authorizes $18,000,000 in FY 89 through FY 91 for such activities.

The Committee acknowledges that there are good activities currently administered by the Center for Devices and Radiological Health at the Food and Drug Administration, which provide several types of services to small businesses that manufacture medical devices. The workshops, educational video tapes, reference manuals and personal contact made available through telephone or correspondence in order to answer questions of manufacturers, are recognized by the Committee as critical to the continued success of innovative small businesses.

Since most small businesses do not have the resources to keep up with the extensive number of government regulations required by the agency, the Committee directs that funds under this section be used to establish similar programs in all of the centers at the FDA.

TITLE V—BIOTECHNOLOGY

Chapter VIII of the Federal Food, Drug, and Cosmetic Act is further amended to provide the Secretary the authority to establish and implement a demonstration project and requires that regulations be issued describing how any public or private cooperative may use the facilities to perform the activities authorized under the Act. The Committee believes that this nation is at the beginning of a new frontier which will shape the economic future of this country for many decades to come. This frontier is in the field of biotechnology, which holds enormous potential for the development of new products in medicine, agriculture and the environment.

The Committee recognizes the development of products in biotechnology requires the use of highly specialized facilities, some requiring impervious walls, specialized air handling systems and drainage connected to tanks that can be steam-sterilized in order to prevent accidents. The Committee further realizes that while such facilities would be extremely expensive for small research firms to construct, many firms could afford to lease space and equipment if it were made available.

Due to the enormous resources being dedicated in this field by foreign countries and the high degree of competitiveness that has emerged for the development of biotechnology products, the Committee believes that is a need for a facility to be developed in the United States where small research organizations who are unable to finance the construction of extremely expensive space required for containment of the products of biotechnology, can come togeher

to share that space and the sophisticated scientific equipment required of this work. Through use of such a facility, the Committee believes that firms not only would have opportunities to develop new research ideas, they would be able to dramatically reduce the time from research to market, a need most commonly identified by economic analysts are being critical to the future success of the United States in this major developing industry.

The Committee has been informed that such a facility already exists. The government owns approximately 400,000 square feet of this high-level containment. The Committee understands that it is part of a very active and highly respected biological research facility in central Arkansas, the National Center for Toxicological Research, NCTR. Constructed in the early 1950s for the containment of biological weapons as part of the U.S. Army's Pine Bluff Arsenal, the Committee understands that the entire facility was demilitarized in 1970–71 and has been turned over to research on toxic compounds.

The Committee believes that a key element of this type of project is the co-location on site of representatives of the regulatory agencies responsible for approving biotechnology products, the FDA, EPA, USDA, and U.S. Patent Office. The Committee recognizes the importance of having prospective review of scientific plans to assure that the necessary types of research will be conducted with the aim of producing an approvable application in the shortest time possible. The Committee has been informed that ample space and facilities exist in that immediate area to house these additional needs at the NCTR site. The costs of renovation would eventually be recovered through the leases to industrial tenants.

TITLE VI—REGULATORY REVIEW MEDICINE TRAINING GRANTS

The Committee believes that in order to continue to protect the public health and maintain its leadership, more trained scientists must be trained in regulatory review medicine. Therefore, S. 2468 provides the Commissioner of the Food and Drug Administration the authority to make grants to public and private non-profit institutions to develop programs to train health professionals and scientists in the field of regulatory review medicine. Such programs will be part of a post-graduate curriculum in conjunction with health professions or science institutions.

As used in this subsection, the term "health professionals and scientists" is intended to apply broadly to the range of scientific disciplines which are relevant to the regulatory responsibilities of the FDA vis-a-vis food, drugs, medical devices, and cosmetics. Thus, the term embraces such disciplines as toxicology, nutrition, food science, and microbiology, as well as the array of other disciplines which are most relevant to the regulation of pharmaceuticals and medical devices.

Subtitle B "Training Grants for Scientist" provides the authority for the Commissioner to enter into agreements for the repayment of loan obligations on behalf of individuals who have completed a curriculum leading to a speciality in regulatory review medicine and are willing and able to be assigned to a position by the Com-

missioner of the Food and Drug Administration for a period of time commensurate with the level of loan payment.

The Public Health Service (PHS) Act provides authorities in several different sections which relate to the award of grants and to traineeships provided through grants. Under currently delegated broad authority, the Commissioner can award grants for research, investigation, and testing programs as well as health information and health promotion programs. Although the Commissioner has this broad authority to award grants, he does not currently have the specific authority under those sections of the Act to award grants for training in regulatory review medicine. The sections of the PHS Act pertaining to grant awards either identify another PHS agency or agencies and their activities without authority currently being delegated to FDA, or the provisions are limiting and preclude FDA's participation.

The Committee believes that in order to continue to protect the public health it is vitally important that the FDA be provided the necessary authority under Title VIII to award multi-purpose training grants to one or more academic institutions to develop a core curriculum program which will be used to train individuals in the field of regulatory review medicine. Many of the areas now regulated by FDA involve products that were unknown when the Food, Drug, and Cosmetic Act was enacted in 1938. The Congress and the American public expect FDA to keep pace with what it regulates.

In recent years FDA has reviewed and approved increasing numbers of products developed through biotechnology—a revolutionary new type of bioscience which has generated revolutionary pharmaceuticals and devices. Similarly, the Agency is currently evaluating new food products such as sweeteners and fats formulated through radically new technological processes.

In the immediate future, FDA will need additional personnel who are trained in the latest technologies in order to respond to the new challenges confronting the Agency. One such challenge is AIDS. The review of all new drug applications continues to be a very high priority for FDA. The Agency has placed special emphasis on producing the most timely, effective, and efficient research and premarketing review possible of products that offer promise for treating, curing, or preventing AIDS or AIDS-related diseases. The Committee believes that it is critical to assure sufficient drug reviews to process expeditiously all Investigational New Drug Applications, New Drug Applications and applications for licensing of AIDS products and vaccines. The Agency, particularly under the leadership of its present Commissioner, Frank E. Young, has established innovative measures to help expedite the development, testing, review, and approval of promising drugs, vaccines, and diagnostics for this disease. Several critically important AIDS-related products have been developed and approved in record breaking time.

The Agency's success in this instance does not, however, mitigate the problems that it now faces. In order to access a new generation of biotech drugs and computer-driven medical devices, FDA's scientific base must be continually revitalized to keep abreast of the latest technological advances.

Title VIII would allow FDA to use allocated funds to address this problem at its source, i.e., the academic institutions which would develop and keep current the appropriate curriculum for evaluating highly advanced medical proposals. It would also assure FDA that persons with the necessary expertise are committed to a specific length of service as medical reviewers within the Agency. The Committee believes that implementation of Title VIII will enable FDA to recruit medical reviewers who are familiar with the latest technological breakthroughs. This, in turn, will expedite society's access to important advanced new pharmaceuticals, medical devices, and food products that could dramatically improve the health and well-being of the American people.

TITLE IX—SCIENTIFIC REVIEW GROUPS

This Committee supports allowing the Commissioner of the FDA to be select members of scientific review groups to assist in reviewing FDA activities and in making recommendations on various issues at FDA. Such scientific review groups shall be exempt from the provisions of the Federal Advisory Committee Act. This provision is consistent with other Public Health Service Agencies, including ADAMHA and NIH.

V. Committee Action

S. 2468 was considered by the Committee on July 14, 1988, and reported favorably with an amendment in the nature of a substitute, by unanimous vote.

VI. CBO Estimate

U.S. Congress,
Congressional Budget Office,
Washington, DC, August 5, 1988.

Hon. Edward M. Kennedy,
Chairman, Committee on Labor and Human Resources,
U.S. Senate, Washington, DC.

Dear Mr. Chairman: The Congressional Budget Office has prepared the attached cost estimate for S. 2468, a bill to revitalize the Food and Drug Administration, as ordered reported by the Senate Committee on Labor and Human Resources on July 14, 1988.

If you wish further details on this estimate, we will be pleased to provide them.

Sincerely,

James Blum,
Acting Director.

CONGRESSIONAL BUDGET OFFICE—COST ESTIMATE

1. Bill number: S. 2468.
2. Bill title: None.
3. Bill Status: As ordered reported by the Senate Committee on Labor and Human Resources on July 14, 1988.
4. Bill purpose: To revitalize the Food and Drug Administration (FDA), and for other purposes.
5. Estimated cost to the Federal Government:

[By fiscal years, in millions of dollars]

Estimated authorization levels	1989	1990	1991	1992	1993
Senior biomedical scientific service	4	4	4	5	5
Increase FTE authority for staff	13	13	14	14	15
Small business training and technical assistance	18	18	18	.....	.....
Biotechnology facilities demonstration project	10	10	11	.....	.....
Regulatory review medicine training grants	4	4	4	.....	.....
Scientific training grant load repayment program	2	2	2	.....	.....
Total estiamted authorization level	51	52	53	19	20
Total estimated outlays	44	49	52	23	21

Note: Details in this table may not add to totals due to rounding. The costs of this bill fall within budget function 550.

Basis of Estimate: The CBO assumes that all authorizations are fully appropriated at the beginning of each fiscal year. Authorization levels not specified in the bill were estimated by CBO. Outlays are estimated using spendout rates computed by CBO on the basis of recent program data.

The bill would authorize the Secretary of Health and Human Services (HHS) to create a Senior Biomedical Scientific Service program to retain scientists within HHS. This program would raise the salary limit for senior scientists and is estimated to cost about $4 milion in fisal year 1989, increasing to about $5 million in 1993. The Public Health Service estimates that 500 scientists would fall into this category and that the initial salary incrase would be about $8,000 for each scientist.

S. 2468 would authorize additional full-time equivalent staff positions (FTEs) within the FDA. Under the bill, not more than 350 employees could be added to the total number employed by the FDA on July 1, 1987. CBO's estimate of the cost of this provision assumes that the maximum number of FTE's permitted by the bill would be employed in 1989–1993. Annual costs of the additional FTE's are estimated by using current average costs, adjusted for projected inflation, of FDA's General Schedule (GS) employees. The average salary of an FDA GS employee is $36,435 in fiscal year 1989.

The bill authorizes appropriations of $18 million in each of the fiscal years 1989 through 1991 for small business training and technical assistance. In addition, the bill specifies an authorization for fiscal year 1989 for the biotechnology facilities demonstration project, but such sums as may be necessary are authorized in fiscal year 1990 and 1991 for this project. The 1990 and 1991 amounts were estimated by increasing the 1989 level for inflation.

The Secretary is authorized to make training grants to academic institutions to establish core curriculum programs in regulatory review medicine. In fiscal year 1989, $4 million is authorized and such sums as may be necessary for fiscal year 1990 and 1991. The 1990 and 1991 levels were estimated by increasing the 1989 level for inflation.

In addition, S. 2468 would establish a science training grant loan repayment program within the FDA. This progarm would pay off a student's loan obligations in return for service; an individual would owe one year of service for each $20,000 paid off. The bill specifies an authorization level of $2 million for fiscal year 1989 and such

sums as may be necessary for fiscal years 1990 and 1991. The 1989 level was inflated to estimate the authorization levels for fiscal years 1990 and 1991.

6. Estimated cost to State and local government: None.

7. Estimate comparison: None.

8. Previous CBO estimate: None.

9. Estimate prepared by: Lori Housman (226–2820).

10. Estimate approved by: C. G. Nuckols for James L. Blum, Assistant Director for Budget Analysis.

VII. Regulatory Impact Statement

The Committee has determined that there will be minimal or no increase in the regulatory burden of paperwork as a direct result of this bill.

VIII. Section-by-Section Analysis

S. 2468—A bill to revitalize the Food and Drug Administration, and for other purposes.

As reported by the Senate Committee on Labor and Human Resources;

TITLE I—REAL PROPERTY

Section 101 of the bill, amends Chapter VII of the Food, Drug, and Cosmetic Act by establishing the Secretary of Health and Human Services as the authority to negotiate transactions for real property, buildings and facilities utilized by the Food and Drug Administration.

TITLE II—SENIOR BIOMEDICAL SCIENTIFIC SERVICE

Amends Section 241 of the Public Health Service Act by adding a new section, "Section 301A—Biomedical Scientific Service." The purpose of this section is to establish a biomedical scientific service. Scientists with distinguished records of achievement in biomedical research or clinical research evaluation will be appointed by the Secretary to perform duties that require expertise in biomedical research, behavioral reseach or clinical research evaluation. Provisions are made for attractive compensation rates and for maintaining the continuity of employment in the Public Health Service.

The term biomedical research and clinical research evaluation are used in this subsection to apply to the range of disciplines relevant to the scope of the FDA's regulatory activities managed at the Food and Drug Administration; these disciplines include chemistry, microbiology, nutrition, pharmacology and medical technology.

TITLE III—INCREASED FTE AUTHORITY FOR STAFF

Section 301 of the bill, authorizes the Secretary of Health and Human Services through the Commissioner of the Food and Drug Administration to add 350 full-time employees to its current staff, in accordance with the civil service and classification laws.

TITLE IV—SMALL BUSINESS TRAINING AND TECHNICAL ASSISTANCE

Section 401 of the bill amends Section 10 of the Medical Device Amendments of 1976 to authorize $18,000,000 in FY89 through FY91 for training and technical assistance to small businesses.

TITLE V—BIOTECHNOLOGY

The Secretary is to establish and implement a biotechnology demonstration project. The authorization level will be $10,000,000 in fiscal year 1989, and further sums in 1990 and 1991.

TITLE VI—REGULATORY REVIEW MEDICINE TRAINING GRANTS

Section 601. Regulatory Review Medicine Training Grants

Section 601 amends the Federal Food, Drug, and Cosmetic Act by creating a new "Chapter X—Training Grants and Loan Repayment," and a new subchapter. New Subchapter A (sections 1001-1005) sets forth provisions for "Regulatory Review Medicine Training Grants."

New section 1001 authorizes the Secretary of DHHS to make grants to public and private nonprofit academic institutiions to develop programs to train individuals in the field of regulatory review medicine.

New section 1002 sets forth the requirements for awarding grants. Institutions must follow Secretary-directed guidelines to guarantee that individuals receiving grant funds will meet the service obligation of section 1004.

New section 1003 sets forth how an institution should use a regulatory review medicine training grant. Institutions receiving these grants should train health professionals and scientists in a core curriculum program developed with its major emphasis on regulatory review medicine. Participants in this program may be provided stipends, tutition, fees and other allowances such as travel.

New section 1004 requires a service obligation from each individual who receives funds under these training grants. Upon completion of training, such individuals are required to be employed with the Food and Drug Administration (FDA) for a time period equal to two months for each month they receive funds. The Secretary will determine the period of time after training completion for compliance.

New section 1005 authorizes appropriations of $4,000,000 for FY 1989 and such sums as necessary for FY 1990 and FY 1991.

Section 602. Science Training Grant Loan Repayment Program

Section 602 amends the new Chapter X of the Federal Food, Drug, and Cosmetic Act by adding a new "Subchapter B—Science Training Grant Loan Repayment Program."

New section 1010 establishes a Science Training Grant Loan Repayment Program (hereinafter referred to as the "Loan Repayment Program") and sets forth criteria for participation and obligations. Eligible participants must: (1) be full-time students in accredited institutions, and (2) be enrolled in a regulatory review medicine training program. Alternatively, qualified participants must (1) have a degree in medicine, osteopathy, dentistry, or some other

health profession, and must have completed an approved graduate regulatory review medicine training program, unless the Secretary waives the latter requirement; (2) be qualified for FDA employment; (3) apply to participate in the Loan Repayment Program; and (4) submit a signed written contract to accept repayment of educational loans and to fulfill the obligated service requirement. The section requires the Secretary to give priority to applicants with training in regulatory review medicine, and a health profession or other needed specialty, and to applicants committed to service with FDA. A loan repayment under the Loan Repayment Program will consist of payment for tuition expenses, other reasonable educational expenses such as fees, books and laboratory expenses, or living expenses as determined by the Secretary. The section makes provisions for loan payments of up to $20,000 on behalf of participants, for each year of obligated service. In addition, if Loan Repayment Program payments result in an increased tax liability for the participant, the Secretary, on request of an affected individual, may make reimbursements to offset the liability. The section requires the Secretary to submit a report to the Congress by March of each year on the number of participants, and type of health profession of Loan Repayment Program participants; the name of the institution at which the participant is being trained; the total number of such applications filed in the current year, as well as prior years; and, the amount of loan payment made in the year being reported on.

New section 1011 sets forth obligatory service requirements for participants of the Loan Repayment Program. The Secretary must determine if the participant will provide this service as a member of the Commissioned Corps of the Public Health Service or a civilian employee.

New section 1012 makes provisions for breach of contract. The Secretary will by regulation determine penalties for an individual who breaches the contract to begin or complete his service obligation.

New section 1013 provides for transportation expenses incurred when the individual moves himself, his family, and his possessions to his duty station location.

New section 1014 authorizes appropriations of $2,000,000 for FY 1989 and such sums as necessary for FY 1990 and FY 1991.

TITLE VII—SCIENTIFIC REVIEW GROUPS

The Commissioner of Food and Drugs is given the authority to appoint members of technical and scientific review groups. Such groups are to be exempt from the provisions of the Federal Advisory Committee Act; under the current law members of scientific review groups at the Food and Drug Administration are recommended by the Commissioner but they must be approved by the Secretary.

IX. Changes in Existing Law

In compliance with rule XXVI paragraph 12 of the Standing Rules of the Senate, the following provides a print of the statute or the part of section thereof to be amended or replaced (existing law

proposed to be omitted is enclosed in black brackets, new matter is printed in italic, existing law in which no change is proposed is shown in roman):

FEDERAL FOOD, DRUG, AND COSMETIC ACT

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CHAPTER VII—GENERAL ADMINISTRATIVE PROVISIONS

REGULATIONS AND HEARINGS

SEC. 701–709. * * *

AUTHORITIES REQUIRED BY THE FOOD AND DRUG ADMINISTRATION REGARDING REAL PROPERTY, BUILDINGS, AND FACILITIES

SEC. 710. The Secretary shall have the following general powers in connection with real property, buildings, and facilities—

(1) to acquire, in any lawful manner, such personal or real property, or any interest in such property, as the Secretary determines necessary or convenient in the transaction of the business of the Food and Drug Administration;

(2) to hold, maintain, sell, lease, or otherwise dispose of property acquired under paragraph (1), or any interest in such property, and to provide services in connection with such property and charges for the use of such property, when appropriate;

(3) to design, construct, operate, lease, and maintain buildings, facilities, equipment, and other improvements on any property owned or controlled by the Food and Drug Administration, including, without limitation, any property or interest therein transferred to the Administration under any other paragraph;

(4) to acquire buildings, facilities, equipment, and make other improvements on any property owned, acquired, or controlled by the Food and Drug Administration through the use of lease-purchase or lease-construction contracts, when and as appropriate; and

(5) to accept gifts or donations of services or property, real or personal, as the Secretary determines necessary in the transaction of the business of the Food and Drug Administration.

USE OF FACILITIES

SEC. 711. (a) IN GENERAL—The Secretary shall establish an implement a demonstration project that authorizes the Secretary to use the facilities of any public or private cooperative, with the permission of any such cooperative, to perform any of the activities authorized under this Act.

(b) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section, $10,000,000 in fiscal year 1989, and such sums as are necessary in each of the fiscal years 1990 and 1991.

(c) REGULATIONS.—The Secretary shall promulgate regulations necessary to carry out this section.

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CHAPTER IX—MISCELLANEOUS

SEPARABILITY CLAUSE

SECS. 901-902. * * *

SCIENTIFIC REVIEW GROUPS

SEC. 903. The Commissioner of Food and Drugs may, without regard to the provisions of title 5, United States Code, governing appointments in the competitive service and without regard to the provisions of chapter 51 and subchapter III of chapter 53 of such title relating to classification and General Schedule pay rates, establish such technical and scientific review groups as are needed to carry out the functions of the Administration, including functions under the Federal Food, Drug, and Cosmetic Act, and appoint and pay the members of such groups, except that officers and employees of the United States shall not receive additional compensation for service as members of such groups. The Federal Advisory Committee Act shall not apply to the duration of a peer review group appointed under this section.

CHAPTER X—TRAINING GRANTS AND LOAN REPAYMENT

Subchapter A—Regulatory Review Medicine Training Grants

AUTHORITY

SEC. 1001. The Secretary may make grants to, or enter into contracts with, any public or nonprofit academic institution, including schools of medicine, dentistry, and pharmacy to enable such institutions to design and develop core curriculum programs that will be used to train individuals in the field of regulatory review medicine.

REQUIREMENTS

SEC. 1002. (a) IN GENERAL.—No grant shall be arded under this subchapter unless—

(1) the institution has submitted to the Secretary an application for a grant and the Secretary has approved the application; and

(2) the institution provides, in such form and manner as the Secretary shall be regulation prescribe, assurances satisfactory to the Secretary that individuals receiving funds through the institution under such grants will meet the service requirement of section 1004.

(b) APPLICATION.—An application for a grant submitted under subsection (a) shall be in such form, submitted in such manner, and contain such information, as the Secretary may by regulation prescribe.

USE OF GRANTS

SEC. 1003. An institution that receives a grant under this subchapter.—

(1) shall use such grant to—

(A) design and develop a core curriculum program that has as its primary emphasis regulatory review medicine; and

(B) train health professionals and scientists in regulatory review medicine; and

(2) may use such grant to provide stipends, tuition, fees, and allowances (including travel and subsistence expenses and dependency allowances), to individuals who participate in the regulatory review medicine program developed with funds provided under this subchapter.

REQUIREMENT OF SERVICE

SEC. 1004. (a) IN GENERAL.—Each individual who receives funds from an institution through a grant provided under this subchapter shall, in accordance with subsection (c), serve an obligated period of time as an employee of the Food and Drug Administration.

(b) PERIOD OF REQUIRED SERVICE.—For each month for which an individual receives funds in accordance with subsection (a), such individual shall remain employed for two months with the Food and Drug Administration.

(c) COMPLIANCE.—The requirements of this section shall be complied with by any individual to whom it applies within such reasonable period of time, after the completion of such individual's training under the grant received under this subchapter, as the Secretary shall by regulation prescribe.

(d) FAILURE TO COMPLY.—If any individual to whom this section applies fails, within the period prescribed under subsection (c), to comply with such requirements, the United States shall be entitled to recover from such individual an amount determined in accordance with a formula prescribed through regulations issued by the Secretary.

AUTHORIZATION OF APPROPRIATIONS

SEC. 1005. There are authorized to be appropriated to make grants under this subchapter $4,000,000 for fiscal year 1989, and such sums as may be necessary for each of the fiscal years 1990 through 1991.

Subchapter B—Science Training Grant Loan Repayment Program

SCIENCE TRAINING GRANT LOAN REPAYMENT PROGRAM

SEC. 1010. (a) ESTABLISHMENT.—The Secretary shall establish a program to be known as the Science Training Grant Loan Repayment Program (hereinafter in this subpart referred to as the "Loan Repayment Program") in order to assure—

(1) an adequate supply of trained physicians, dentists, and pharmacists; and

(2) an adequate supply of veterinarians and other health professionals as determined to be necessary from time to time by the Secretary.

(b) ELIGIBILITY.—To be eligible to participate in the Loan Repayment Program, an individual must—

(1)(A) be enrolled—

(i) as a full-time student in an accredited educational institution in a State; or

(ii) in a training program in regulatory review medicine as described in regulations issued by the Secretary; or

(B) have—

(i) a degree in medicine, osteophathy, dentistry, or other health profession; and

(ii) completed an approved graduate training program in regulatory review medicine, except that the Secretary may waive the completion requirement of this clause for good cause;

(2) be eligible for employment with the Food and Drug Administration;

(3) submit an application to participate in the Loan Repayment Program; and

(4) sign and submit to the Secretary, at the time of the submission of such application, a written contract (described in subsection (f)) to accept repayment of educational loans and to serve (in accordance with this subtitle) for the applicable period of obligated service with the Food and Drug Administration.

(c) APPLICATION, CONTRACT, AND INFORMATION REQUIREMENTS.—

(1) SUMMARY AND INFORMATION.—In disseminating application forms and contract forms to individuals desiring to participate in the Loan Repayment Program, the Secretary shall include with such forms—

(A) a fair summary of the rights and liabilities of an individual whose application is approved (and whose contract is accepted) by the Secretary, including in the summary a clear explanation of the damages to which the United States is entitled under section 1012 in the case of the individual's breach of the contract; and

(B) such other information as may be necessary for the individual to understand the individual's prospective participation in the Loan Repayment Program.

(2) UNDERSTANDABILITY.—The application form, contract form, and all other information furnished by the Secretary under this subtitle shall be written in a manner calculated to be understood by the average individual applying to participate in the Loan Repayment Program.

(3) AVAILABILITY.—The Secretary shall make such application forms, contract forms, and other information available to individuals desiring to participate in the Loan Repayment Program.

(d) PRIORITY.—In determining which applications under the Loan Repayment Program to approve (and which contracts to accept), the Secretary shall give priority to applications made by—

(1) individuals whose training is in regulatory review medicine and in a health profession or specialty determined by the Secretary to be needed; and

(2) individuals who are committed to service with the Food and Drug Administration.

(e) APPROVAL REQUIRED FOR PARTICIPATION.—

(1) IN GENERAL.—An individual becomes a participant in the Loan Repayment Program only on the Secretary's approval of

the individual's application submitted under subsection (b)(3) and the Secretary's acceptance of the contract submitted by the individual under subsection (b)(4).

(2) WRITTEN NOTICE.—The Secretary shall provide written notice to an individual promptly on—

(A) the Secretary's approving, under paragraph (1), the individual's participation in the Loan Repayment Program; or

(B) the Secretary's disapproving the individual's participation in such Program.

(f) CONTENTS OF CONTRACTS.—The written contract (referred to in this subchapter) between the Secretary and an individual shall contain—

(1) an agreement that—

(A) subject to paragraph (3), the Secretary agrees—

(i) to pay on behalf of the individual loans in accordance with subsection (g); and

(ii) to accept (subject to the availability of appropriated funds for carrying out this subchapter) the individual as being qualified for employment with the Food and Drug Administration; and

(B) subject to paragraph (3), the individual agrees—

(i) to accept loan payments on behalf of the individual;

(ii) in the case of an individual described in subsection (b)(1)(A), to maintain enrollment in a course of study or training described in such subsection until the individual completes the course of study or training;

(iii) in the case of an individual described in subsection (b)(1)(A), while enrolled in such course of study or training, to maintain an acceptable level of academic standing (as determined under regulations of the Secretary by the educational institution offering such course of study or training); and

(iv) to serve for a time period (hereinafter in this subchapter referred to as the "period of obligated service") for a period of time described in regulations issued by the Secretary or such longer period as the individual may agree to, with the Food and Drug Administration;

(2) a provision permitting the Secretary to extend for such longer additional periods, as the individual may agree to, the period of obligated service agreed to by the individual under paragraph (1)(B)(iv);

(3) a provision that any financial obligation of the United States arising out of a contract entered into under this subtitle and any obligation of the individual that is conditioned thereon, is contingent on funds being appropriated for loan repayments under this subtitle;

(4) a statement of the damages to which the United States is entitled, under section 1012, for the individual's breach of the contract; and

(5) such other statements of the rights and liabilities of the Secretary and of the individual, not inconsistent with this subpart.

(g) PAYMENTS.—

(1) IN GENERAL.—A loan repayment provided for an individual under a written contract under the Loan Repayment Program shall consist of payment, in accordance with paragraph (2), on behalf of the individual of the principal, interest, and related expenses on government and commercial loans received by the individual for—

(A) tuition expenses;

(B) all other reasonable educational expenses, including fees, books, and laboratory expenses, incurred by the individual; or

(C) reasonable living expenses as determined by the Secretary.

(2) PAYMENTS FOR YEARS SERVED.—

(A) IN GENERAL.—Except as provided in paragraph (3), for each year of obligated service that an individual contracts to serve under subsection (f) the Secretary may pay up to $20,000 on behalf of the individual for loans described in paragraph (1).

(B) REPAYMENT SCHEDULE.—Any arrangement made by the Secretary for the making of loan repayments in accordance with this subsection shall provide that any repayments for a year of obligated service shall be made no later than the end of the fiscal year in which the individual completes such year of service.

(3) TAX LIABILITY.—In addition to payments made under paragraph (2), in any case in which payments on behalf of an individual under the Loan Repayment Program result in an increase in Federal, State, or local income tax liability for such individual, the Secretary may, on the request of such individual, make payments to such individual in a reasonable amount, as determined by the Secretary, to reimburse such individual for all or part of the increased tax liability of the individual.

(4) PAYMENT SCHEDULE.—The Secretary may enter into an agreeement with the holder of any loan for which payments are made under the Loan Repayment Program to establish a schedule for the making of such payments.

(h) EMPLOYMENT CEILING.—Notwithstanding any other provision of law, individuals who have entered into written contracts with the Secretary under this section, while undergoing academic or other training, shall not be counted against any employment ceiling affecting the Department.

(i) REPORTS.—The Secretary shall, not later than March 1 of each year, submit to the Congress a report specifying—

(1) the number, and type of health profession training, of individuals receiving loan payments under the Loan Repayment Program;

(2) the educational institution at which such individuals are receiving their training;

(3) the number of applications filed under this section in the school year beginning in such year and in prior school years; and

(4) the amount of loan payments made in the year reported on.

OBLIGATED SERVICE

SEC. 1011. (a) GENERAL RULE.—Each individual who has entered into a written contract with the Secretary under section 1010 shall provide service as a full-time employee of the Food and Drug Administration for the period of obligated service provided in such contract.

(b) PROCEDURE FOR SERVICE.—

(1) DETERMINATION OF SERVICE.—If an individual is required under subsection (a) to provide service as specified in section 1010(f)(1)(B)(iv) (hereinafter in this subsection referred to as 'obligated service'), the Secretary shall, not later than 90 days before the date described in paragraph (4), determine if the individual shall provide such service as a member of the Commissioner Corps of the Public Health Service or a civilian employee of the United States.

(2) INFORMATION AND NOTIFICATION.—

(A) PROVISION OF INFORMATION.—If the Secretary determines that an individual shall provide obligated service as a Commissioned Officer, or a civilian employee of the United States, the Secretary shall, not later than 60 days before the date described in paragraph (4), provide such individual with sufficient information regarding the advantages and disadvantages of service as such a commissioned officer or civilian employee to enable the individual to make a decision on an informed basis.

(B) NOTIFICATION.—To be eligible to provide obligated service as a Commissioned Officer, an individual shall notify the Secretary, not later than 30 days before the date described in paragraph (4), of the individual's desire to provide such service as such an officer.

(3) CIVILIAN EMPLOYEES.—If an individual provided notice by the Secretary under paragraph (2) does not qualify for appointment as a Commissioned Officer, the Secretary shall, as soon as possible after the date described in paragraph (4), appoint such individual as a civilian employee of the United States.

(4) NOTIFICATION DATE.—In the case of the Loan Repayment Program, if an individual is required to provided obligated service under such Program, the date referred to in paragraphs (1) through (3)—

(A) shall, in the case of an individual who is enrolled in an approved training program in regulatory review medicine, be the date the individual completes such training program; or

(B) shall be the date the individual enters into an agreement with the Secretary under section 1010.

(c) BEGINNING OF SERVICE.—An individual shall be considered to have begun serving a period of obligated service on the date such individual is appointed as either a Commissioned Officer or a civilian employee of the United States.

BREACH OF CONTRACT

SEC. 1012. The Secretary shall by regulation establish the penalties applicable to an individual that breaches the contract entered

into under section 1010 by failing (for any reason) to begin his service obligation in accordance with an agreement entered into under section 1010, or to complete such service obligation.

TRANSPORTATION EXPENSES

SEC. 1013. The Secretary may pay an individual who has entered into an agreement with the Secretary under section 1010 an amount to cover all or part of the individual's expenses reasonably incurred in transporting himself, his family, and his possessions to the location of his duty station.

AUTHORIZATION OF APPROPRIATIONS

SEC. 1014. There are authorized to be appropriated to make grants under this subchapter $2,000,000 for fiscal year 1989, and such sums as may be necessary for each of the fiscal years 1990 through 1991.

PUBLIC HEALTH SERVICE ACT

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TITLE III—GENERAL POWERS AND DUTIES OF PUBLIC HEALTH SERVICE

PART A—RESEARCH AND INVESTIGATION

IN GENERAL

SEC. 301. * * *

BIOMEDICAL SCIENTIFIC SERVICE

SEC. 301A. (a) ESTABLISHMENT.—The Secretary is authorized to establish a Senior Biomedical Scientific Service (hereinafter in this section referred to as the "Service").

(b) MEMBERSHIP.—

(1) CIVIL SERVICE.—Inviduals chosen to serve in the Service shall not be a part of the competitive service established under chapter 33 of subpart B of part I of title 5, United States Code.

(2) APPOINTMENT.—A person may be appointed to the Service by the Secretary based solely on that person's distinction and achievement in the fields of biomedical research or clinical research evaluation.

(c) DUTIES.—Members of the Service shall be assigned to duties that require expertise in biomedical research, behavioral research, or clinical research evaluation, and may also be assigned to supervise other scientists in carrying out the activities described in this subsection.

(d) COMPENSATION.—Individuals selected to serve on the Service staff by the Secretary under subsection (b), shall be compensated at a rate not in excess of 110 percent of the annual rate of pay in effect for level I of the Executive Salary Schedule established in section 5512 of title 5, United States Code.

(e) RETIREMENT.—For purposes of section 211, the continuous service in the Service of any person who commences such service on termination of service as a commissioned officer in the Public Health

Service Corps may be treated as service as a commissioned officer in the Public Health Service Corps and shall not be considered as service that is subject to any other retirement system for officers and employees of the Federal Government.

MEDICAL DEVICE AMENDMENTS OF 1976

(42 U.S.C. 3512)

§ 3512. Office to assist small manufacturers of medical devices; establishment

(*a*) The Secretary of Health and Human Services shall establish within the Department of Health and Human Services an identifiable office to provide technical and other nonfinancial assistance to small manufacturers of medical devices to assist them in complying with the requirements of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.], as amended by this Act.

(b) There are authorized to be appropriated to carry out the provisions of this section, $18,000,000 in each of the fiscal years 1989 through 1991.

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